

Please correct the title at page 2 of the specification as follows:

METHOD AND APPARATUS FOR MASS-CUSTOMIZED-MANUFACTURING DENTAL ALIGNERS

Please correct the paragraph at page 5, lines 3-10 as follows:

In one aspect, the invention is directed to an apparatus to manufacture dental aligners, including a workpiece introduction system having at least one workpiece preparation chamber. The system further has a mold manipulation system, having a mold introduction chamber, where a series of different molds may be introduced one after the other; a mold preparation chamber; a workpiece operation chamber; and a mold manipulator to move the mold between the mold introduction chamber, ~~the mold preparation chamber, and the workpiece operation chamber; and a workpiece manipulator to move the workpiece between the workpiece preparation chamber and the workpiece operation chamber.~~

Please correct the paragraph at page 7, lines 12-13 as follows:

~~FIG. 3A-L~~ FIGS. 3A and 3B are stepwise schematic views showing an embodiment of a manufacturing method in accordance with the principles of the invention.

Please correct the two paragraphs beginning at page 8, line 10 through page 9, line 2 as follows:

Turning now to the drawings, in which similar reference characters denote similar elements throughout several views, FIG. 1 illustrates one embodiment of a manufacturing apparatus constituting an embodiment of the invention. In particular, FIG. 1 shows a workpiece introduction system in which thermoplastic workpiece preparation and introduction are accomplished via a rotary turret apparatus. A rotary "plastic" ~~turret 12 turret a12~~ is in cooperative engagement with a mold manipulation system, here mold ~~turret 14. turret a14.~~ The plastic turret 12 rotates about a plastic turret axis 44 and the mold turret 14 rotates about a mold turret axis 46. In general, and as will be described in greater detail below, the plastic turret 12 provides various preparatory functions for a

plastic initially sheet-shaped workpiece 71 (see FIG. 3A) (~~see FIG. 3~~) and the mold turret 14 provides the shaping of the workpiece 71 into a formed or finished aligner using the mold.

The plastic turret 12 has various workpiece preparation chambers to perform sequential processing functions in a semi-continuous fashion. These chambers include a proximal loading chamber 18 ~~chamber 18~~ for introduction of workpieces. In this chamber, each workpiece 71, which may have been previously clamped to a cartridge or other clamping system or the like to facilitate its convenient introduction and manipulation, is placed on a workpiece manipulator 41 for introduction into and manipulation within the plastic turret 12. The workpiece 71 then enters the rotary portion of the plastic turret 12 via a distal loading chamber 22. The plastic turret 12 rotates in the direction indicated by a plastic turret direction of rotation 26, which moves the workpiece 71 into the next processing chamber. The workpiece 71 may be heated via an oven 24, the same including a preheater 28 and a heater 30. For example, the temperature of the workpiece 71 may reach 525 to 595 °F in the preheater 28 and about the same or higher in the heater 30. This heating allows the workpiece 71 to become pliable and subject to formation via a mold and plug.

Please correct the paragraph at page 9, lines 13-21 as follows:

The mold turret 14 also has various chambers to perform various functions, and rotates in the direction indicated by a mold turret direction of rotation 42 to allow sequential processing in a semi-continuous fashion. These chambers include a mold-loading chamber 36, a plug-loading chamber 38, the workpiece operation chamber 32, and a mold-preheating chamber 40. The mold may be moved between these chambers via a mold manipulator 43. The mold manipulator 43, which may have a actuator shape to accomplish up-and-down movements, may also be moved such that the mold is in cooperative engagement with a workpiece 71 in the workpiece operation chamber 32. The details of the cooperative engagement and fabrication process are described in greater detail below with regard to FIGS. 3A and 3B. ~~FIG. 3.~~

Please correct the paragraph at page 10, lines 5-12 as follows:

The inline system has certain advantages over the rotary system of FIG. 1. For example, in the inline system, a roll of plastic may be conveniently employed to provide the basic workpiece material, and this roll can be cut into individual workpieces 71 at any time during the fabrication process, including even after the workpiece 71 is formed into a finished aligner 136. In this way, the system may take advantage of assembly line techniques and have each station require nearly the same amount of time, such that each workpiece is worked seriatim. By contrast, in the rotary system, each workpiece 71 must be cut into an individual piece, at the latest, by the time the workpiece 71 enters chamber 20 (FIG. 1). ~~chamber 20.~~

Please correct the paragraph at page 11, lines 11-18 as follows:

In use, and also referring to FIGS. 3A and 3B, ~~FIG. 3A-L,~~ which illustrate stepwise schematic views showing an embodiment of a manufacturing method in accordance with the principles of the invention, a plastic sheet from a roll 58 may emerge through a set of rollers 62 (~~FIG. 3A,~~ step 64), the plastic sheet later to be cut by a cutter 60. After cutting, the cut sheet, now termed a “workpiece 71”, is grasped by a set of clamps or clamping system 76 so that the workpiece 71 may be held securely for further processing (~~FIG. 3B,~~ step 66). Following clamping, the workpiece 71 may be subjected to preheating by an oven 50 (~~FIG. 3C,~~ step 68). The heating allows the workpiece 71 to be made more pliable and thus easier to work.

Please correct the paragraph beginning at page 11, line 27 through page 12, line 16 as follows:

The workpiece 71 is moved into proximity of the mold 90 (~~FIG. 3D,~~ step 70) and the plug 104 (~~FIG. 3E,~~ step 72), see ~~FIG. 3G,~~ step 108. A separate heater 98 may be employed to preheat each of the mold 90 and the plug 104 (~~FIG. 3F,~~ step 74). The workpiece operation chamber 32 may be heated such that the workpiece 71 becomes even more flexible and pliable (~~FIG. 3H,~~ step 110). The mold 90 ~~90~~ and the plug 104 ~~104~~ may be brought into cooperative engagement by action of the mold actuator 88 and the plug actuator 102 (~~FIG. 3I,~~ step 112). The plug 104 helps to ensure that the plastic of the workpiece is pulled over the mold. A vacuum may then be brought to bear on the workpiece 71, on the side of the workpiece 71 opposite that of the plug 104, such that the workpiece

71 achieves an even greater and tighter fit to the mold 90. After the workpiece 71 has achieved the same shape as the mold 90, the mold actuator 88 and the plug actuator 102 may be separated, at which point the mold 90 may be separated from the mold actuator 88 and may fit within the formed workpiece (~~FIG. 3K~~, step 116). The mold 90 may be separated from the mold actuator 88 by the action of an air actuator (~~FIG. 3L~~, step 118). The clamps 76 may be removed. The finished workpiece, now an aligner 136, may be marked for identification as described above and trimmed to remove excess plastic also as described above. The aligners or appliances will be marked in some manner, typically by sequential numbering directly on the appliances or on tags, pouches, or other items which are affixed to or which enclose each appliance, to indicate their order of use. Optionally, written instructions may accompany the system which set forth that the patient is to wear the individual appliances in the order marked on the appliances or elsewhere in the packaging. Use of the appliances in such a manner will reposition the patient's teeth progressively toward the final tooth arrangement.

Please correct the paragraph at page 14, lines 8-17 as follows:

In another embodiment, in-line individually controlled modular ceramic heaters are used in the heat zone. Ceramic heaters with controlled zones are used to achieve required cycle times. An opposing dual platform load station allows continuous rotary introduction of unique molds to web without interruption to the process. This will allow simultaneous loading of the next mold during the forming process. The forming station allows continuous introduction and removal of new unique mold to be thermoformed at each cycle. The pressure/vacuum chamber is first sealed on the web allowing pre-forming to occur. The mold is then introduced to the pre-formed ~~web and web~~ web and simultaneously the vacuum and pressure are applied to form the material on the mold. As the chamber is opened the load platform is withdrawn and the mold is retained in the web and transferred to the machine vision station.

Please correct the paragraphs beginning at page 14, line 27 through page 15, line 19 as follows:

Fig. 6 shows an exemplary process to fabricate units using mass-customization. First, roll material is retrieved from a storage device (111) ~~device (110)~~. The rolled material is controlled and delivered to

a spooler (113). ~~spooler (112)~~. At this stage, the material is in a controlled environment that keeps temperature, moisture and static electricity conditions, among others, within a predetermined tolerance (115). ~~tolerance (114)~~. Next, the roller material is provided to a web feed system (117). ~~system (116)~~. Incoming material is precision aligned, captured and fed (119). ~~capture and fed (118)~~. The material is also provided to a piercing chain for incremental sequencing control (120). The web fed material is provided to a heat zone where the material is heated to create molds in one embodiment (122). The material is heated to a forming temperature (124). A ramp heating system is used with controllable heat elements (126).

The molds are transferred to a load station (128). The molds are first placed on a load station for introduction into a forming station (130). The molds can be manually loaded (132) or can be automatically loaded (134). Next, the roll material is formed over one or more molds (137). ~~molds (136)~~. The heated material is pressure and vacuum formed over the molds (138). In a pre-forming operation, material is blown into a dome shape to provide a uniform thickness (140). The mold is introduced into the pre-formed dome shape (142), and pressure and vacuum is applied to form the device (144).

The formed material includes part identification (ID), which is detected by machine vision using a camera and light ring (150). A 2D ID code is read and a corresponding file for the part is retrieved over the network (152). ~~network~~. The 2D data matrix bar code is formed directly on the unit (154). A hot-stamp contrast of the 2D code is performed to improve readability (156). The output of the vision camera with light ring is communicated for marking purposes (158). ~~purposes~~.

Please correct the paragraph beginning at page 16, line 19 through page 17, line 31 as follows:

Next, the aligners 136 are packed and trays and labels are applied to the packages. The resulting packages are then shipped to customers. Typically the appliances are to be worn in a particular sequence to provide desired treatment, such as a progressive movement of teeth through a variety of arrangements to a final desired arrangement. In one embodiment, a system of dental appliances is provided comprising a plurality of dental appliances wherein at least some of the plurality include a non-numeric indicia designating an order in which each of the at least some of the plurality are to be

worn by a patient to provide dental treatment. Typically, each of the plurality of dental appliances comprise a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement. In some embodiments, each of the polymeric shells has at least one terminal tooth cavity and the indicia comprises a terminal tooth cavity of differing length in each of the polymeric shells. In other embodiments, each of the polymeric shells has shell ~~has~~ a height and the indicia comprises a different height in each of the polymeric shells. In still other embodiments, the indicia comprises one or more cutouts so that each polymeric shell has a different cutout pattern. Sometimes the cutout comprises a notch in an edge of the appliance. In yet other embodiments, the indicia comprises a color wherein each appliance has different color. The color of the appliances may have the same hue and vary by intensity, for example. The color may comprise a dissolvable dye. Or, the system may further comprise a wrapper removably attachable to each of the appliances, wherein each wrapper has the color. In another embodiment, a system of packaged dental appliances is provided comprising a plurality of packages each containing a dental appliance, wherein the plurality of packages are joined in a continuous chain designating an order in which each of the dental appliances are to be worn by a patient to provide dental treatment. In some instances, the packages are each joined by a perforation wherein the packages can be separated by breaking the perforation. In other instances, the packages are joined by, for example, a heat seal. Further, the system may include a marking on a package at an end of the chain indicating the dental appliance to be worn first. Again, each of the plurality of dental appliances may comprise a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement. In yet other embodiments, a system of dental appliances is provided comprising a plurality of dental appliances to be worn by a patient to provide dental treatment, and a framework, wherein each of the plurality of dental appliances are removably attached to a portion of the framework. In some embodiments, each of the plurality of dental appliances comprises a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement. Further, the system may comprise at least one marking on the framework indicating the order in which the appliances are to be worn by a patient. In still another embodiment, a plurality of packages are produced wherein each of the packages includes a polymeric shell having cavities shaped to receive and resiliently reposition teeth from one arrangement to a successive arrangement, the plurality of packages ~~package~~ including a first package containing a first shell to be worn by the patient to reposition the teeth from the one

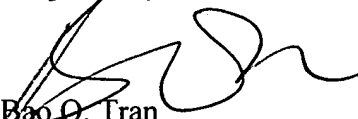
arrangement to the successive arrangement and a second package containing a second shell to be worn by the patient to reposition the teeth from a ~~from the~~ successive arrangement to another successive arrangement. The first package can be provided to the patient at a designated time through a remote delivery system, and delivering the second package to the patient at a later designated time through the remote delivery system. In most embodiments, the remote delivery system comprises a mail delivery system.

The request for corrected Filing Receipt filed May 26, 2004 correcting the title of the application to "**METHOD AND APPARATUS FOR MANUFACTURING DENTAL ALIGNERS**" is resubmitted concurrently herewith. The above amendment corrects the title on the first page of the specification to be consistent with that requested title correction.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at 408-470-1243.

Please charge any required fees to Deposit Account No.: 50-1399.

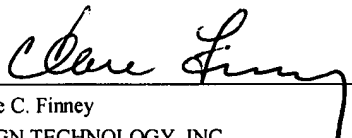
Respectfully submitted,


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On July 8, 2004

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